

CLAIMS:

1. An isolated 55P4H4-related protein.
2. The 55P4H4-related protein of claim 1, wherein the 55P4H4-related protein has at  
5 least 6 contiguous amino acids of an amino acid sequence shown in SEQ ID NO: 2.
3. The 55P4H4-related protein of claim 1, wherein 55P4H4-related protein has at least  
7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, or more than 25 contiguous amino  
acids of an amino acid sequence shown in SEQ ID NO: 2.
4. The 55P4H4-related protein of claim 1, wherein the 55P4H4-related protein is at  
10 least 30, 35, 40, 45, 50, 55, 60, 65, 70 or more than 70 contiguous amino acids of an amino acid  
sequence shown in SEQ ID NO: 2.
5. The 55P4H4-related protein of claim 1, wherein the 55P4H4-related protein includes  
an amino acid sequence selected from the group consisting of amino acid residues 5-10, 8-10, 14-17,  
30-33, 85-87, 96-99, 102-107, 149-151, 188-191, of SEQ ID NO: 2.
- 15 6. An 55P4H4-related protein of claim 1 that comprises an HLA class I A1, A2, A3,  
A24, B7, B27, B58, B62 supermotif, or an HLA class II DR supermotif set forth in Table IV (B) or an  
Alexander pan DR binding epitope supermotif or an HLA DR3 motif.
7. An 55P4H4-related protein of claim 1 that comprises at least one conservative  
substitution.
- 20 8. An 55P4H4-related protein of claim 1 that comprises an epitope that induces a  
specific antibody response.
9. The 55P4H4-related protein of claim 1, wherein the 55P4H4-related protein has the  
amino acid sequence shown in SEQ ID NO: 2.
10. The 55P4H4-related protein that is at least 90% homologous to an amino acid  
25 sequence of claim 1.
11. The 55P4H4-related protein that is at least 90% identical to an amino acid sequence  
of claim 1.

12. An isolated 55P4H4-related protein of claim 1 that has an amino acid sequence which is exactly that of an amino acid sequence encoded by a polynucleotide selected from the group consisting of:

- 5
- (a) a polynucleotide consisting of the sequence as shown in SEQ ID NO: 1, wherein T can also be U;
- (b) a polynucleotide consisting of the sequence as shown in SEQ ID NO: 1, from nucleotide residue number 204 through nucleotide residue number 782, wherein T can also be U;
- 10
- (c) a polynucleotide that encodes a 55P4H4-related protein whose sequence is encoded by the cDNAs contained in the plasmid designated p55P4H4-EBB12 deposited with American Type Culture Collection as Accession No. PTA-1894;
- (d) a polynucleotide that encodes an 55P4H4-related protein that is at least 90% homologous to the entire amino acid sequence shown in SEQ ID NO: 2;
- 15
- (e) a polynucleotide that encodes an 55P4H4-related protein that is at least 90% identical to the entire amino acid sequence shown in SEQ ID NO: 2;
- (f) a polynucleotide that is fully complementary to a polynucleotide of any one of (a)-(e); and,
- (g) a polynucleotide that selectively hybridizes under stringent conditions to a polynucleotide of (a)-(e).
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13. A pharmaceutical composition comprising a 55P4H4 polynucleotide and a pharmaceutically acceptable carrier, wherein the polynucleotide is selected from the group consisting of:

- 5 (a) a polynucleotide consisting of the sequence as shown in SEQ ID NO: 1, wherein T can also be U;
- (b) a polynucleotide consisting of the sequence as shown in SEQ ID NO: 1, from nucleotide residue number 204 through nucleotide residue number 782, wherein T can also be U;
- 10 (c) a polynucleotide that encodes a 55P4H4-related protein whose sequence is encoded by the cDNAs contained in the plasmid designated p55P4H4-EBB12 deposited with American Type Culture Collection as Accession No. PTA-1894;
- (d) a polynucleotide that encodes an 55P4H4-related protein that is at least 90% homologous to the entire amino acid sequence shown in SEQ ID NO: 2;
- 15 (e) a polynucleotide that encodes an 55P4H4-related protein that is at least 90% identical to the entire amino acid sequence shown in SEQ ID NO: 2;
- (f) a polynucleotide that is fully complementary to a polynucleotide of any one of (a)-(e); and,
- (g) a polynucleotide that selectively hybridizes under stringent conditions to a polynucleotide of (a)-(e).
- 20

14. A pharmaceutical composition of claim 13, wherein the polynucleotide encodes a 55P4H4-related protein, and wherein the polynucleotide consists of the sequence as shown in Figure 2 (SEQ ID NO: 1), from nucleotide residue number 204 through nucleotide residue number 782, wherein T can also be U.

25 15. A pharmaceutical composition of claim 13, wherein the polynucleotide encodes a 55P4H4-related protein, wherein the polypeptide includes an amino acid sequence selected from the group consisting of amino acid residues 5-10, 8-10, 14-17, 30-33, 85-87, 96-99, 102-107, 149-151, 188-191, of SEQ ID NO: 2.

30 16. A pharmaceutical composition of claim 13, wherein the polynucleotide encodes an 55P4H4-related protein, wherein the protein comprises an HLA class I A1, A2, A3, A24, B7, B27,

B58, B62 supermotif, or an HLA class II DR supermotif set forth in Table IV (B) or an Alexander pan DR binding epitope supermotif or an HLA DR3 motif.

17. A pharmaceutical composition comprising a recombinant expression vector that contains a polynucleotide of claim 13, and a pharmaceutically acceptable carrier.

5 18. A pharmaceutical composition comprising a host cell that contains an expression vector of claim 17, and a pharmaceutically acceptable carrier.

19. A process for producing a 55P4H4-related protein comprising culturing a host cell of claim 18 under conditions sufficient for the production of the polypeptide and recovering the 55P4H4-related protein so produced.

10 20. A 55P4H4-related protein produced by the process of claim 19.

21. An antibody or fragment thereof that specifically binds to a 55P4H4-related protein.
22. The antibody or fragment thereof of claim 24, that specifically binds to a portion of the 55P4H4-related protein, wherein the portion is selected from the group consisting of amino acid residues 5-10, 8-10, 14-17, 30-33, 85-87, 96-99, 102-107, 149-151, 188-191, of SEQ ID NO: 22.
- 5 23. The antibody or fragment thereof of claim 21, which is monoclonal.
24. A recombinant protein comprising the antigen-binding region of a monoclonal antibody of claim 23.
25. The antibody or fragment thereof of claim 21, which is labeled with a detectable marker.
- 10 26. The recombinant protein of claim 24, which is labeled with a detectable marker.
27. The antibody fragment of claim 21, which is an Fab, F(ab')<sub>2</sub>, Fv or Sfv fragment.
28. The antibody of claim 21, which is a human antibody.
29. The recombinant protein of claim 24, which comprises murine antigen binding region residues and human constant region residues.
- 15 30. A non-human transgenic animal that produces an antibody of claim 21.
31. A hybridoma that produces an antibody of claim 23.
32. A single chain monoclonal antibody that comprises the variable domains of the heavy and light chains of a monoclonal antibody of claim 23.
- 20 33. A vector comprising a polynucleotide that encodes a single chain monoclonal antibody of claim 32 that immunospecifically binds to a 55P4H4-related protein.

34. An assay for detecting the presence of a 55P4H4-related protein or polynucleotide in a biological sample comprising steps of:

contacting the sample with an antibody or another polynucleotide, respectively, that specifically binds to the 55P4H4-related protein or polynucleotide, respectively; and,

5 detecting the binding of 55P4H4-related protein or polynucleotide, respectively, in the sample thereto.

35. An assay of claim 34 for detecting the presence of an 55P4H4-related protein or polynucleotide comprising the steps of:

obtaining a sample,

10 evaluating said sample in the presence of an 55P4H4-related protein or polynucleotide, whereby said evaluating step produces a result that indicates the presence or amount of 55P4H4-related protein or polynucleotide, respectively.

36. An assay of claim 35 for detecting the presence of an 55P4H4 polynucleotide in a biological sample, comprising:

15 (a) contacting the sample with a polynucleotide probe that specifically hybridizes to a polynucleotide encoding an 55P4H4-related protein having an amino acid sequence shown in Figure 2; and

(b) detecting the presence of a hybridization complex formed by the hybridization of the probe with 55P4H4 polynucleotide in the sample, wherein the presence of the hybridization complex  
20 indicates the presence of 55P4H4 polynucleotide within the sample.

37. An assay for detecting the presence of 55P4H4 mRNA in a biological sample comprising:

(a) producing cDNA from the sample by reverse transcription using at least one primer;

5 (b) amplifying the cDNA so produced using 55P4H4 polynucleotides as sense and antisense primers to amplify 55P4H4 cDNAs therein, wherein the 55P4H4 polynucleotides used as the sense and antisense probes are capable of amplifying the 55P4H4 cDNA contained within the plasmid as deposited with American Type Culture Collection as Accession No. PTA-1894;

(c) detecting the presence of the amplified 55P4H4 cDNA,

38. A method for monitoring 55P4H4 gene products comprising:

10 determining the status of 55P4H4 gene products expressed by cells in a tissue sample from an individual;

comparing the status so determined to the status of 55P4H4 gene products in a corresponding normal sample; and

15 identifying the presence of aberrant 55P4H4 gene products in the sample relative to the normal sample.

39. A method of monitoring the presence of cancer in an individual comprising: performing the method of claim 38 whereby the presence of elevated 55P4H4 mRNA or protein expression in the test sample relative to the normal tissue sample provides an indication of the presence or status of a cancer.

20 40. The method of claim 39, wherein the cancer occurs in a tissue set forth in Table I.

41. A pharmaceutical composition comprising a substance that modulates the status of a cell that expresses 55P4H4.

42. A pharmaceutical composition of claim 41 that comprises an 55P4H4-related protein and a physiologically acceptable carrier.

5 43. A pharmaceutical composition of claim 41 that comprises an antibody or fragment thereof that specifically binds to a 55P4H4-related protein and a physiologically acceptable carrier.

44. A pharmaceutical composition of claim 41 that comprises a polynucleotide that encodes a single chain monoclonal antibody that immunospecifically binds to an 55P4H4-related protein and a physiologically acceptable carrier.

10 45. A pharmaceutical composition of claim 41 that comprises a polynucleotide comprising a 55P4H4-related protein coding sequence and a physiologically acceptable carrier.

46. A pharmaceutical composition of claim 41 that comprises an antisense polynucleotide complementary to a polynucleotide having a 55P4H4 coding sequence and a physiologically acceptable carrier.

15 47. A pharmaceutical composition of claim 41 that comprises a ribozyme capable of cleaving a polynucleotide having 55P4H4 coding sequence and a physiologically acceptable carrier.

48. A method of treating a patient with a cancer that expresses 55P4H4, the method comprising steps of:

20 administering to said patient a vector that comprises the composition of claim 44, such that the vector delivers the single chain monoclonal antibody coding sequence to the cancer cells and the encoded single chain antibody is expressed intracellularly therein.

49. A method of inhibiting in a patient the development of a cancer that expresses 55P4H4, the method comprising:

administering to the patient an effective amount of the composition of claim 41.

25 50. A method of generating an immune response directed to 55P4H4 in a mammal, the method comprising:



exposing the mammal's immune system to an immunogenic portion of an 55P4H4-related protein of claim 1 or a nucleotide sequence that encodes said protein, whereby an immune response is generated to 55P4H4.

51. A method of delivering a cytotoxic agent to a cell that expresses 55P4H4, said  
5 method comprising:

conjugating the cytotoxic agent to an antibody or fragment thereof of claim 21 that specifically binds to a 55P4H4 epitope; and,

exposing the cell to the antibody-agent conjugate.

52. A method of inducing an immune response to an 55P4H4 protein, said method comprising:

providing a 55P4H4-related protein of claim 1 that comprises at least one T cell or at least one B cell epitope;

5 contacting the epitope with an immune system T cell or B cell respectively, whereby the immune system T cell or B cell is induced.

53. The method of claim 52, wherein the immune system cell is a B cell, whereby the induced B cell generates antibodies that specifically bind to the 55P4H4-related protein.

54. The method of claim 53, wherein the immune system cell is a T cell that is a  
10 cytotoxic T cell (CTL), whereby the activated CTL kills an autologous cell that expresses the 55P4H4 protein.

55. The method of claim 52, wherein the immune system cell is a T cell that is a helper T cell (HTL), whereby the activated HTL secretes cytokines that facilitate the cytotoxic activity of a CTL or the antibody producing activity of a B cell.